Original Article

A cross-sectional audit of informed consent of online survey: Characteristics and adherence to prevalent guidelines

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Abstract

Background: Research on human participants requires formal approval from a competent ethics committee. During the recruitment of the research participants, obtaining informed consent is a prerequisite. The online survey method is used by many researchers as it can collect the data from a diverse population in a short time.

Aim: This study aimed to observe the characteristics and adherence to prevalent guidelines (set by the *Indian Council of Medical Research* [ICMR]) of informed consent coupled with online surveys.

Methods: We collected the informed consent text from online survey links obtained from a network of colleagues who got a request to participate in a survey. Data were collected from July 2020 to June 2022. The text was anonymized for further analysis. The word count, sentences, and Flesch reading ease score were calculated. The adherence to ICMR guidelines where checked by two authors individually and a consensus was reached to prepare the final result.

Results: A total of 44 online surveys in English were audited and among them, 10 did not have informed consent. The informed consent in 34 surveys had a median of 6 sentences and 84 words. The median reading ease score was 45.7 (college level). The majority of the consent states the purpose of the research (91.18%), the voluntary nature of the participation (85.29%), and mentioned that it is research (64.71%). However, the rest of the components are ignored by the majority of the survey consent form.

Conclusion: Informed consent form with online surveys lacks adherence to the components suggested by ICMR. Hence, the forms should be made carefully by the researchers so that the vigor of informed consent is maintained in the online surveys.

Keywords: Biomedical research, consent forms, ethics committees, informed consent, surveys and questionnaires

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INTRODUCTION

Any research on human participants or animal requires formal approval from a competent ethics committee. When the researchers recruit the research participants for the study, they recruit only the participants who enroll themselves voluntarily. This is done by obtaining informed consent. For clinical trials and other invasive research, informed consent is an extensive affair and of utmost

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importance for maintaining ethical research practice.[1] There are guidelines set by the Indian Council of Medical Research (ICMR) on how to frame an informed consent form and the essential and additional components to adhere to.[2]

Surveying people is a method of collecting data where the researchers can collect a huge amount of data in a short period. Due to higher smartphone usage and the availability of internet connection in India, an online survey is being used instead of a paper-based survey in many cases. An online survey is more aggressive in terms of wide reach, less time, and digitized data.[3] A survey link may reach millions of people via social media and the researchers may get a response within minutes of posting the survey links from potential respondents. The data received are digital; hence, no need to manually enter the data into a computer program for further analysis.[4]

For conducting a survey online, the researcher commonly shares the link of the survey with a short text message. The participants read and if interested, participate in the survey by clicking on the survey link. This is the reason why many of the researchers may think it is not necessary to obtain full informed consent as there are very minor chances of potential discomfort to participants in a self-administered questionnaire.[5] However, this assumption should be avoided for ethical and transparent research work. According to the National Ethical Guidelines for Biomedical and Health Research published by ICMR in 2017, a "researcher must obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants (5.0)." Online surveys involve "human participants" and collect some information that is analyzed for meaningful research output. Although the preceding quoted sentence indicate that "written informed consent" should be obtained, ICMR also clarifies that "electronic media can be used to provide information as in the written informed consent document, which can be administered and documented using electronic informed consent systems (5.5)." Hence, online consent is a valid method to recruit research participants. However, the researcher must be careful in designing the form as "the electronic consent must contain all elements of informed consent in a language understandable by the participant (5.5.2)."[6]

Several previous studies have evaluated the characteristics of informed consent in clinics and research. Joolaee *et al*. evaluated the informed consent before the surgical intervention in a hospital situated in Iran and found that the quality of the consent form is grossly deficient technically, medically, and legally.[7] Malik *et al*. reviewed 112 informed consent of clinical trials related to cancer treatment in Australia and found that the consent forms are designed as per the guidelines and still can be improved technically.[8] Choudhary *et al*. studied the informed consent form prepared by postgraduate students of Maharashtra, India, and found that the majority of the informed consent forms were prepared following standard guidelines but missed some of the elements.[9] To the best of our knowledge, the characteristics and completeness of the informed consent of online surveys have not been explored in India.

Hence, we aimed to observe the characteristics of the informed consent of online surveys and compare the elements of the consent text with guidelines laid by ICMR for the preparation of the informed consent form. The result of this study would provide us information if the online surveys are being conducted with properly informed consent forms with all elements. If found deficient, stakeholders may strengthen the training and practice surveillance for a complete informed consent process in line with offline surveys or research.

METHODS

This study involves an audit of the anonymized text coupled with online surveys. Any identification of the surveys is not divulged. This study was conducted from July 2020 to June 2022. This study was approved by the Institutional Ethics Committee (REF/IEC/021/2019).

During the study period, the survey requests received by first two authors and the survey requests received by the colleagues of the authors were collected for the study. The text message shared with the survey link was also collected. The survey links were opened and responses were filled up to the last question to search for the informed consent text. However, the survey form was never submitted. The informed consent text was collected and any identifying information was removed and stored for further analysis.

The text of the message was thematically analyzed by the first author. The presence or absence of informed consent was counted. If the consent text was there, the signing method was stored. The text of the informed consent was observed for the sentence count, word count, words per sentence, syllables per word. Flesch-Kincaid reading ease score and grade level was calculated from https://goodcalculators.com/flesch-kincaid-calculator.[10] The method was previously used by studies concerned with assessing the ease of reading in India.[11,12]

A list of the essential component of an ideal consent was prepared from the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017.[6] The guidelines suggests 10 components that "must" be included and four components that "may also be required" according to the nature of the study. In the essential 10 components, there are some components where combinations of attributes are there. For example, a component (second point in the Box 5.1 in the guideline) has both "purpose" and "methods" and another has "duration," "type" of data collection, and "methods" of data collection (third point in the Box 5.1 in the guideline). Hence, we separated those and finally got 13 components. If we decided to keep those combined attributed under a single component, bias might appear in marking presence or absence of it in a consent form. For example, a consent form may have the "purpose" and may not have the "method." The text of the informed consent form was scrutinized by the first two authors individually and a meeting was arranged to find any discrepancies and final consensus for the preparation of the final result.

Statistical analysis

The data were expressed in number, percentage, mean, standard deviation, median, minimum and maximum, and quartiles according to necessity. The distribution of the data was tested by the Shapiro–Wilk test. As the data were not normally distributed, nonparametric tests were used. One-sample median test and Kruskal–Wallis *H* test were used for continuous data and the Chi-square test for categorical data.[13] A $P < 0.05$ was considered statistically significant. For descriptive statistical tests, we used Microsoft Excel 2010 (Microsoft Corporation, USA) and for inferential statistical tests, we used GraphPad Prism 6.01 (GraphPad Software, USA). For qualitative data analysis and and theme generation along with its frequencies, we used Qualitative Data Analysis (QDA) Miner Lite version 2.0.8 (Provalis Research, Montreal, Canada).

RESULTS

Among the 44 survey invitations, 10 (23%) had no informed consent statements. Among the rest of the survey invitations (77%) where we found informed consent, 36% had only the text in the survey, and the rest of the invitations had a mandatory agree button to click [Figure 1]. A graphical presentation shows the methods of obtaining informed consent in online surveys in Figure 2.

The text message along with the survey link had some elements of informed consent like the importance of the survey, the voluntary nature of the participation, data security, and contact information [Table 1]. A request to participate in the survey is very common (68.18%) with the survey link. The time to complete the survey is the next common element of the message. Further thematic analysis is shown in Table 1.

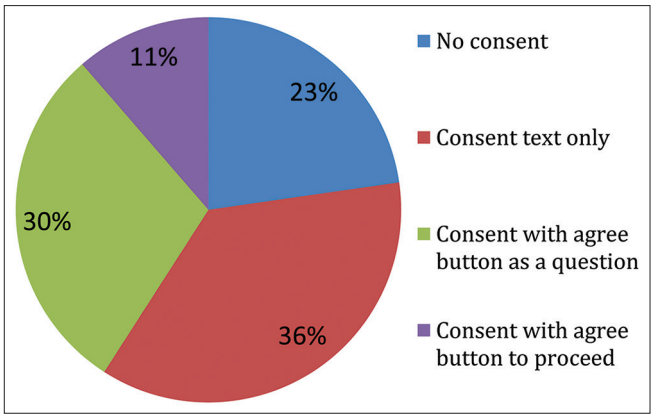

Figure 1: Consent in online survey form ($n = 44$) (Chi-square $P = 0.11$)

The informed consent texts had a median of 6 (Q1-Q3: 6–12) sentences and 84 (Q1-Q3: 65–173) words. The median reading ease score was 45.7 (Q1-Q3: 35.1–49.5). It indicates that a college student would understand the text without difficulty and a median grade level of 10.8 (Q1-Q3: 9.7–11) is required to read and understand the text [Table 2].

The adherence of the informed consent to guidelines by ICMR is shown in Table 3. The majority of the consent states the purpose of the research (91.18%), the voluntary nature of the participation (85.29%), and mentioned that it is research (64.71%). However, the rest of the components are ignored by the majority of the survey consent form. When analyzed with coding compliance, we found a mean score of 4.324 ± 3.435 which was far below the total score of 13 (one-sample median test $P < 0.0001$).

DISCUSSION

With an aim to find the characteristics of the text of the informed consent form coupled with online surveys, first, we found that about 23% of the surveys do not have a consent form. The ICMR guideline 2017 provides a waiver for certain types of research where there is "less than minimal risk to participants and the waiver will not adversely affect the rights and welfare of the participants (5.7 and Box 5.2)." The majority of the online survey may fall in the "less than minimal risk." Hence, this may be a ground for a waiver. However, ICMR further specified that the waiver may be given in research where - (a) Research cannot be conducted without waiver, (b) Obtaining consent is

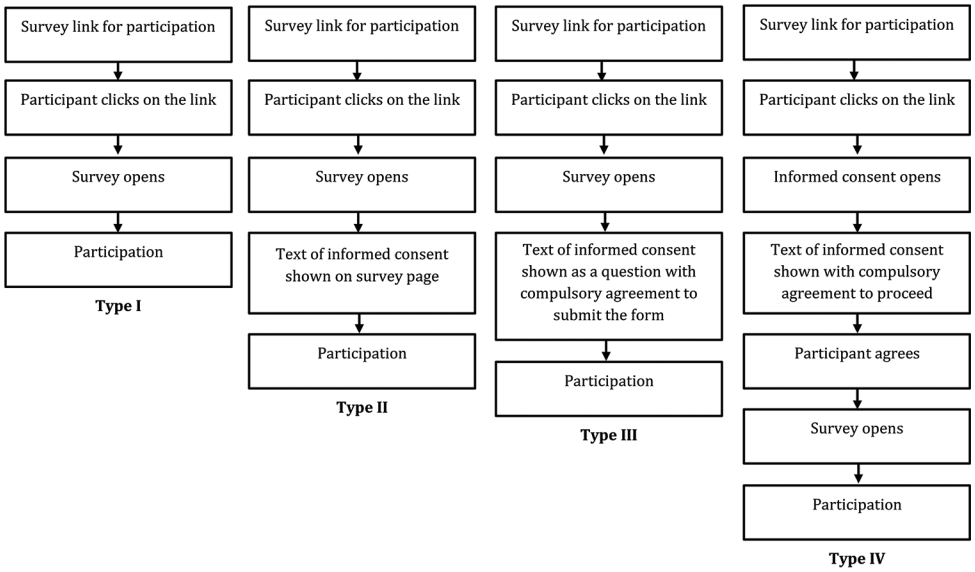

Figure 2: Schematic to present various types of informed consent agreement in online surveys

Table 1: Thematic analysis of text with link of the survey (*n*=44)

Theme	*n* (%)	Example quoted text
Request	30 (68.18)	"I request you to kindly participate and make the survey a successful one"
Time	25 (56.82)	"It will take only 4-5 min of your time"
Importance	19 (43.18)	"It will reveal the current exercise barriers among"
Voluntary	17 (38.64)	"Please participate voluntarily in this survey"
Benefit	15 (34.09)	"About the current knowledge on (disease) and plan IEC activity"
Anonymity	15 (34.09)	"We are not collecting any identity details"
Data security	14 (31.82)	"We keep the data secure and will not share for any commercial gain"
Contact	13 (29.55)	"For any queries, you can contact me on (cell phone number)"
Target participant	7 (15.9)	"If you are a medical student studying MBBS (any semester), please"

IEC=Information education communication

Table 2: Text characteristics of the informed consent text (*n*=34)

Statistics	Sentence	Word	Word/sentence	Syllables/word	Flesch-Kincaid grade level	Flesch-Kincaid reading ease score
Minimum	4	44	7.3	1.7	8.1	29.8
Q1	6	65	9.625	1.7	9.7	35.1
Median	6	84	12.8	1.7	10.8	45.7
Q3	12	173	13.68	1.9	11	49.5
Maximum	20	257	22.2	2	13.1	53.5
Mean±SD	8.91±4.68	119.47±65.48	12.43±3.82	1.79±0.12	10.31±1.22	43.19±8.13

Flesch-Kincaid reading ease score: 0-30: very difficult; >30-50: difficult; >50-60: fairly difficult; >60-70: standard; >70-80: fairly easy; >80-90: easy; >90-100: very easy[9]. Q1=First quartile, Q3=Third quartile, SD=Standard deviation

not possible (e.g., retrospective study), (c) Research with anonymized biological sample or data, (d) Study involving public domain (data on a website that anyone can access and use) data, (e) Research in a humanitarian emergency, and (f) Some program evaluation and surveillance program (Box 5.2).[6] The "anonymized biological sample or data" is sometimes considered a waiver for consent in online surveys. However, online surveys are not fully anonymous as the responder can be traced by the internet protocol address. Those who are collecting data on Google Forms and not collecting the E-mail address of the participants are also not fully anonymized data collection as the respondents' E-mail addresses are collected by Google (the company that provides the survey platform). Table 4 shows the possibility of waiver of consent for a paper-based and electronic survey on different grounds suggested by ICMR. As online surveys are having minimal risk and full freedom of participation, a waiver may be considered. However, the components of a consent form not only appraise the participants for a glimpse of the study but also provide information about voluntary participation, especially for a special group of participants. For example, a student may think his/her compulsory participation is necessary for a survey conducted by his/her teacher when no consent form is provided. In contrast, when the student gets the informed consent statements in detail, he/she

Table 3: Adherence of informed consent to Indian Council of Medical Research guidelines (*n*=34)

Component	Yes (%)	Mean±SD
Mention it is a research	22 (64.71)	0.647±0.485
Purpose of research	31 (91.18)	0.912±0.288
Method of research	15 (44.12)	0.441±0.504
Duration and frequency of contact	4 (11.76)	0.118±0.327
Type of data collection	14 (41.18)	0.412±0.499
Method of data collection	5 (14.71)	0.147±0.359
Benefits to participant, community or others	9 (26.47)	0.265±0.448
Foreseeable risks, discomfort or inconvenience	2 (5.88)	0.059±0.239
Confidentiality of records	4 (11.76)	0.118±0.327
Payment or reimbursement for participation	3 (8.82)	0.088±0.288
Treatment and/or compensation for research-related harm	2 (5.88)	0.059±0.239
Freedom to participate or withdraw anytime	29 (85.29)	0.853±0.359
Identity of research team and contact persons	7 (20.59)	0.206±0.41
Overall score (sum of 13 component)	-	4.324±3.435

Coding (yes=1, no=0) was done to find mean±SD. One-sample median test was conducted with overall score with comparing with hypothetical value of 13 and result showed a $P<0.0001$. Kruskal-Wallis *H*-test (nonparametric analysis of variance) was conducted to know if inter-component score varies significantly and the result showed $P<0.0001$. Dunn's *post hoc* test showed significant difference in 27 pairs among the 78 pairs. SD=Standard deviation

Table 4: Possibility of waiver of consent in prospective survey collecting data from human research participants

Ground[6]	Possibility of waiver	
	Paper-based survey	Electronic survey
Less than minimal risk to participants and the waiver will not adversely affect the rights and welfare of the participants	Yes (?)	Yes
Research cannot practically be carried out without the waiver and the waiver is scientifically justified	No	No
Retrospective studies, where the participants are de-identified or cannot be contacted	Not applicable	Not applicable
Research on anonymized "biological samples"/data	Yes	Yes (?)*
Certain types of public health studies/surveillance programs/program evaluation studies	Yes	Yes
Research on data available in the public domain	Not applicable	Not applicable
Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent	Yes	Yes

*Although online surveys collected data from anonymous users, the participants may be traced by internet protocol address. Hence, it may not be called fully "anonymized data."(?)=May be or may not be appropriate according to situations assessed by competent committee

understands the right of voluntary participation. Hence, considering obtaining full informed consent would help conduct transparent recruitment of participants.[14]

We found that the text of informed consent can be understood by a person having formal education for 11 years (Class 11 or 1st year of 10 + 2 course) with a reading ease score range of 30–50 which indicates the English is difficult to understand. A well-designed informed consent form is of utmost importance for a proper understanding of the consent. We have analyzed only the English consent form of the surveys. English is not the mother tongue of the Indian population, although it is one of the major media of formal education and for other mediums, the majority of the students have English as their second language. Hence, people with formal education would understand English but difficulty may be faced. Hence, a careful selection of common words, short sentences, and values of the cultural aspect should be remembered during the design of the informed consent form.[15] Technical and medical terminologies should be minimized to a possible level. A study by Santel *et al.* found that the grade level of the informed consent form is 10th to college grade. Furthermore, Perni *et al.* from the USA found that the readability of the written consent form is not following the national recommended level (8th Grade).[16] The finding is corroborative with our study. However, the grade should ideally be 6th to 8th Grade which corresponds to the 80–90 Flesch-Kincaid reading ease score.[17]

The message shared with the online survey link has some components of informed consent like voluntary participation in the survey along with the aim of the survey. Many of the surveys also declare the benefit of the survey, anonymity, security of the data, and contact information of the surveyor. This is obviously a good practice to include the text on the message shared with the link of the survey. The participants get a fair idea about the survey before clicking the survey link. However, which components should be part of the text is still not guided by any research body. We presume that the message may have short sentences about the target participants (for whom it is meant), that the survey is research, the aim of the survey, benefits, voluntary participation, and contact information. In our current study, we found that the details about target participants are mentioned in a few messages. This may be due to the perception of the researchers that the link would be shared with the snowball sample or

shared in some closed social media where the sample has similar characteristics. However, this presumption may be wrong as due to ease of sharing the survey link may reach to undesired target. Hence, the statement about the target participant should be written along with the message with the survey link.[18]

Many of the Indian languages may not be supported by the survey platform. However, informed consent in the local language should be provided for a better understanding of the research and participation.[19] In that case, the consent form in the local language may be provided as an additional attachment with a clear description that the consent is available in the local language in the attached portable document format file. However, the major limitation of the informed consent process in an online survey is that the researchers do not have any idea how much the participant understands the consent form. This cannot be avoided and should be a declared limitation of all online surveys. Informed consent is a legal requirement for any survey and not merely a formality and the signature in a form by a participant implies a full understanding of the participation.[20] However, in an online survey, a signature is not commonly obtained due to the difficulty of obtaining the signature. Instead, an innovative form of digital agreement is recorded and that is valid in India.[6,21] From the current study, we found four types of methods to obtain agreement for participation as shown in Figure 2. All of them ensure that participation is voluntary. However, we presume that for a robust method of consent, Type IV is better than the other three methods.

The compliance of the informed consent forms of the online survey revealed that they are grossly deficient to fulfil the criteria laid by the ICMR guidelines. Similar to our study, although not concerned with an online survey, a study by Vučemilo and Borovečki from Croatia found that although the forms have some of the essential elements, the forms are not perfectly designed for the Croatian general population.[22] There may be multiple underlying reasons for this finding. The researchers may not have formal training in research ethics and informed consent procedure. The ethical committee may skip the meticulous review of the informed consent form. The researcher may not have the checklist to prepare the consent form. However, in this study, we did not explore the reason for the deficiencies. It would be a future research topic.

Novelty and limitation

This study reports the characteristics of informed consent in online surveys and their adherence to standard guidelines from India. As access to the informed consent of online surveys is difficult, the sample size is relatively low in this study. Although informed consent from the ethics committee review boards might be obtained and that could yield a higher sample size. However, there might be a difference between the submitted consent (to the ethics committee) form and the actual consent form online. Hence, we only included consent forms of actual surveys. The data were collected from the survey invitations received personally, in social media groups, and via a closed group of colleagues. This is the major limitation of the study in that the sampling has a high level of bias and is clustered to a professional group. However, this was the only method we could adapt to collect the survey invitations for a period of 2 years. The readers should be aware that convenience sampling is a nonprobability sample that limits generalization. Further studies involving a large sample would be conducted for a more generalizable result.

CONCLUSION

The message sent along with online survey links has some elements of informed consent that help the participants to get a glimpse of the informed choice for participation. However, the message is not a complete informed consent form. Many of the online surveys do not have informed consent at all. This is against the ethical conduct of research. The texts of the informed consent were understandable to an 11th-Grade student. However, further simplification may help in better understanding. The essential components of informed consent are missing from the majority of the informed consent form of online surveys. A training program for researchers and careful review by the ethics committee may help to design properly informed consent forms for online surveys.

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Conflicts of interest

There are no conflicts of interest.

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